

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed June 6, 2011. Claims 17, 36-44, 50, and 52-59 were pending and rejected in view of cited art.<sup>2</sup> Claims 17, 36, 50, 56, and 58-59 are amended. Claims 17, 36-44, 50, and 52-59 are now pending in view of the above amendments, of which claims 17, 36, and 50 are the independent claims.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. EXAMINER INTERVIEW**

Applicant's express their appreciation to the Examiner for conducting an interview with Applicant's representative on September 14, 2010. The substance of the interview is included in this response.

### **A. INFORMATION DISCLOSURE STATEMENTS**

Applicant has reviewed the Examiner's comments regarding the Information Disclosure Statements filed on 10/28/2010, 11/02/2010, 11/05/2010, 11/11/2010, 11/29/2010, 12/7/2010, 12/13/2010, 12/23/2010, 1/11/2011, 1/18/2011, 01/24/2011, 1/26/2011, 20/03/2011, 02/23/2011, 03/02/2011, 03/08/2011, 03/15/2011, 03/17/2011, 03/25/2011, 03/28/2011, 04/05/2011, 04/13/2011, 04/29/2011, 05/09/2011, and 05/18/2011 and is sympathetic to the burden of

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<sup>2</sup> Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

reviewing the references cited therein. Applicant wishes to make clear that the number of references cited therein does not reflect any attempt to "bury" references, nor has Applicant submitted "a mountain of largely irrelevant material." Instead, Applicant has made a good faith effort to submit all references that have come to its attention and that fall within categories that might arguably render the references material, so that the Examiner may have the benefit of all possibly material information and so as to preclude any allegation that Applicant has not fully complied with its duty of candor and good faith.

**B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Office Action rejected claims 17, 37-44, 58, and 59 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claim 17 has been amended to remove the term generally from the phrase "the generally annular-shaped body." Claims 58 and 59 have been amended to recite "the plurality of looped elements" rather than "the spring elements." Thus, Applicant respectfully requests removal of these rejections.

**C. PRIOR ART REJECTIONS**

**I. REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejected claims 17, 37, 39-44, 50, 52, and 54-59 under 35 U.S.C. § 103(a) as being unpatentable over International Publication No. WO 99/62408 (Derowe). Claim 36 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Derowe in view of U.S. Patent No. 7,169,158 (Sniffen). Claims 38 and 53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Derowe as applied to claim 17 and 52, further in view of U.S. Patent No. 6,488,692 (Spence).<sup>3</sup> As discussed in the interview, and as presented herein for reconsideration, independent claims 17, 36, and 50 and their depending claims are neither

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<sup>3</sup> The dependent claims were rejected as obvious over Derowe in view of Sniffen, and/or Spence. While the arguments herein are focused on the differences between the independent claims and the prior art of record, which differences are equally applicable to the dependent claims, this does not mean that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicant thus does not acquiesce in any asserted rejections of the dependent claims. Any assertion in the Office Action not expressly traversed as to any dependent claims is not intended to constitute, and should not be construed as, an acquiescence on the part of Applicant as to the purported teachings or prior art status of the cited references, as to the characterization of the cited references advanced by the Examiner, or as to any other assertions, allegations or characterizations made by the Examiner. Applicant reserves the right to challenge the purported teaching of the cited references or any judicial notice asserted at any appropriate time.

anticipated nor made obvious by Derowe, Sniffen, or Spence, either singly or in combination with any other prior art of record, and thus favorable reconsideration is respectfully requested.

Vascular closure devices are used to facilitate closure of a puncture site in a body lumen. A puncture site may be closed by bringing the edges of the puncture together. Improved closure may be achieved by bringing both the edges and at least a portion of the internal surface of the body lumen together. Merely bringing the edges together may be insufficient in cases where the puncture site does not, for example, provide a symmetrical clean edge. Applicant has developed a closure device for engaging tissue at the puncture site in a way that provides more effective closure of the puncture site.

As presented herein for reconsideration, Applicant's claimed invention comprises (see independent claim 17, as exemplary) a device for engaging tissue at a puncture site and facilitating closure of the puncture site. The device comprises an annular-shaped body that defines a plane and is disposed about a central axis extending substantially normal to the plane. The body includes a plurality of looped elements that extend about a periphery of the body to form an endless sinusoidal pattern. The device also comprises a plurality of tines having free distal ends extending from the looped elements through the central axis of the generally annular-shaped body. The body and tines include a resilient material so that the body and tines normally lie in a planar, deployed first configuration. The material of the body and tines is sufficiently resilient so that when a force is applied to the tines they are forced from the planar, deployed first configuration into a transverse, pre-deployment second configuration in which the tines and free distal ends are spread open for insertion of the free distal ends into the tissue around the puncture site. Thereafter, the body and tines will automatically return toward the first configuration so as to engage the puncture site and facilitate closure thereof after the force is removed.<sup>4</sup>

Derowe is concerned with vascular port devices. Specifically, Derowe describes, among other things, self-sealing anastomotic devices, (p. 1, ll. 25-26). The Office Action cited Derowe as disclosing "a plurality of tines (382) having free distal ends that extend from the looped elements and towards the central axis of the annularly shaped body," (Office Action, page 5)(emphasis added).

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<sup>4</sup> Independent claims 36 and 50 are similar. Claims 36 differs from claim 17 by adding a further limitation that requires that the tines are "arcuate." Claim 50 differs from claim 17 by adding a further limitation that requires that the tines are "substantially straight."

However, independent claims 17, 36, and 50 have been amended to recite, in part, that the plurality of tines "extend . . . through the central axis of the annularly shaped body." The Office Action has not cited, nor has Applicant found, any portion of Derowe that discloses, teaches, or suggests this limitation. Rather, as shown, and described by Derowe and as presently understood by Applicant, the anchors 386 either always extend out of plane or extend toward, but not to, the central axis. Furthermore, Derowe teaches away from anchors that "extend . . . through the central axis of the annularly shaped body," because Derowe is concerned with providing access through the vascular port device. Hence, every embodiment shown and described by Derowe extends toward but not to the central axis. Therefore, Derowe teaches away from any reference with tines that "extend . . . through the central axis," as recited, in part, by claims 17, 36, and 50.

Thus, as will be appreciated, Derowe's vascular port devices are significantly different from the devices for engaging tissue at a puncture site and facilitating closure of the puncture site claimed by Applicant, and does not teach or suggest a device having, that the plurality of tines "extend . . . *through* the central axis of the annularly shaped body" (independent claims 17, 36 and 50, emphasis added).<sup>5</sup> There being no other rejections of record, and for at least the reasons noted, independent claims 17, 36 and 50 are patentable over the prior art of record. Indeed, as noted in the Interview Summary prepared by the Examiner at the interview's conclusion, proposed "amendment stating that the tines extend through the central axis of the annular-shaped body overcomes the prior art of record." Thus, favorable reconsideration and allowance is respectfully requested.

**D. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any

Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 30<sup>th</sup> day of October, 2011.

Respectfully submitted,

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<sup>5</sup> The secondary references to Sniffin and Spence were also briefly discussed at the interview, and it was acknowledged that these references were much less relevant than those discussed above, and add nothing beyond those references relating to the distinctions of the claims over the prior art, as noted.